Immediate / Lidocaine Hydrochloride Injection / Hospira RECALL (01/14)

Reason/Information:

FDA Class I Recall has been issued on the following medical materiel. Reason: Due to Reddish Orange particulate on the inner surface and floating in the solution. If particulate goes undetected and solution is administered, the particle may potentially block the infusion of the solution to the patient, resulting in a delay in therapy. If smaller pieces of the particulate break off and become free floating within the solution, they may pass through the catheter into the patient, resulting in local inflammation or mechanical disruption of tissue. Chronically, following sequestration, local granuloma formulation is possible. In consideration of the reddish orange color of the particulate, if there is iron within the particle that is infused, it may put a patient at risk when undergoing MRI (strong magnetic field exposure), as the particle could potentially be dislodged and be pulled through tissue, causing local inflammation and tissue trauma. Hospira believes the embedded particulate is related to a supplier's glass defect.

Disposition/Instructions:

Immediately stop use and quarantine. Return product to Stericycle. Hospira will be notifying direct customers via recall letter. For return instructions contact Stericyle at 855-695-8596 or 317-860-1188. Additional questions or clinical inquiries, contact Hospira; Hospira Global Complaints call 800-441-4100, (ProductComplaintsPP@hospira.com). Hospira Medical Communcations call 800-615-0187, (medcom@hospira.com) or 224-212-2000.

Item Information:

NSN (FSC-NIIN): 6505-015213228
NDC: 00409206605
Nomenclature: LIDOCAINE HYDROCHLORIDE INJECTION, USP, 20MG/ML, 5 ML VIAL, 10S
UI: PG
Manufacturer: HOSPIRA

LOT / SN:
32-135-DD

NOTES:

NOTE 1:
"This product is not a direct match with the above listed NSN, however, the Medical Master Catalog indicates that it may be associated."
NSN (FSC-NIIN): 6505-016007488
NDC: 00409206605
Nomenclature: LIDOCINE HYDROCHLORIDE INJECTION, USP, 20MG/ML, 5ML VIAL, 25S
UI: PG
Manufacturer: HOSPIRA

LOT / SN:
32-135-DD

NOTES:

NOTE 1:
"This product is not a direct match with the above listed NSN, however, the Medical Master Catalog indicates that it may be associated."

POC Contact Information:

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Additional Message Recipients:

Please ensure widest dissemination of information to all interested entities.

Message Dissemination Authorization:

US AIR FORCE
AF Activities Will Take Action As Prescribed In AFI 41-209, Medical Logistics Support, Chapters 3 And 9. For MAJCOMS & Ngb--This Msg Has Been Transmitted To All Designated Subordinate Medical Activities.

US ARMY
See Army Regulation (Ar) 40-61, 28 January 2005, Chapter 4, And The Department Of The Army Supply Bulletin (Sb 8-75-11) For Applicable Policies And Procedures.